



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM

DATE: December 22, 1998

TO: Kathleen Meier, CRM
Special Review and Reregistration Division

FROM: David Farrar, Statistician, EFED task leader for ODM
Jim Breithaupt, Fate and Exposure scientist.
Environmental Risk Branch II
Environmental Fate and Effects Division (7507C)

THROUGH: Betsy Grim, Acting Branch Chief
EFED/ERB II

RE: **Oxydemeton-methyl (30 day registrant response):**
EFED RED chapter for the ODM docket;
Partial Response to Gowan comments;
Terrestrial chronic risk

This communication responds to the request from SRRD for an up-to-date copy of the EFED RED chapter for placement in the Oxydemeton-methyl (ODM) docket. For the docket, SRRD may use the draft that we transmitted most recently (Sept. 11, 1997). An electronic copy is provided along with the electronic version of this memo. Also, we respond to some issues that the registrant (Gowan Co.) has raised, in the following communication:

Gowan Comments on EFED's memo dated Sept. 11, 1997 and the draft Reregistration Eligibility Decision Chapter for Oxydemeton-methyl" (2/16/98)

The major issues raised by Gowan have to do with whether or not there is a need to mitigate risks to honeybees, assessment of chronic avian exposure and risk, and requirements for fate and effects

data for ODM metabolites. As discussed informally with the ODM CRM, issues related to risk mitigation and data requirements will be addressed at a later time; in this communication we only comment on the terrestrial exposure and risk.

EFED does not propose bottom-line changes of the RED chapter at this time based on Gowan's communication. An attachment indicates a minor revision in the wording of the RED text to clarify the results of the avian reproduction study MRID 40747202.

Summary of Gowan's analysis. Gowan disputes that there is a basis for chronic terrestrial concerns. The major arguments appear to be that EFED over-estimated both the chronic toxicity and the time-0 (initial) exposure. Regarding the dissipation rate on foliage, Gowan's assumptions appear similar to EFED's.

Regarding chronic toxicity, according to Gowan's interpretation of the bobwhite quail reproduction study (MRID 40747202) the NOEC should be 6.9 ppm and not the value of 1.8 indicated in the RED chapter.

Regarding exposure, Gowan submits summaries of crop residue information for corn, alfalfa, and cole crops from trials conducted in several states. The values reported by Gowan for an individual trial represent the concentration immediately following the last of 1-7 applications, based on the reasoning that these values will include the contribution from previous applications. Gowan calculates an average residue measurement for each crop, averaging over trials in different states. The resulting average values are 10.3 ppm for corn, 10.9 ppm for alfalfa, and 3.4 ppm for cole crops, based on an application rate of 0.5 lb ai/A. The corresponding ranges of results for individual trials are 5-23.5 ppm for corn (15 trials), 4-26 ppm for alfalfa (13 trials), and 0.4-9.9 for for cole crops (18 trials). Gowan states that "average residues are the appropriate values to consider for chronic risk assessment."

Instead of calculating risk quotients, Gowan compares the NOEC to the residue that they estimate for 7 days following application. Gowan assumes:

- The maximum one-time label rate of 1.88 lb ai/A based on a citrus label;
- 10.9 ppm on foliage per 0.5 lb ai/A applied, based on the residue data they report for alfalfa;
- 84% reduction in foliage residue after 7 days;
- NOEC = 6.9 ppm;

Gowan calculates that the residue would decline to 6.6 ppm after 7 days, which is 96% of the NOEC.

Gowan argues that chronic impacts would not be expected unless exposure is maintained close to the duration of the chronic study (21 weeks).

Response. After reviewing the arguments and information submitted by Gowan, EFED concludes that chronic effects on birds are plausible and therefore it is appropriate to conclude that there is a “concern.”

Regarding chronic toxicity, EFED will continue to use the NOAEC of 1.8 ppm. The exposure data advocated by Gowan suggests concentrations immediately following application that are significantly lower than the values EFED has assumed. The data come from types of studies that are not standard for terrestrial exposure assessment and without further review EFED can neither confirm nor deny that the data is suitable for use in ecological risk assessment.. However, it appears that the data would not refute the chronic concern if it is used.

The major disagreements between the assessments from EFED and Gowan appear to be as follows:

1. EFED will continue to use 1.8 ppm as the NOEC for avian reproductive effects for ODM based on the bobwhite reproduction study. The RED misreported the results of the study. The RED suggested that effects were observed at 6.9 ppm but not at 17.3 ppm for weight of hatchlings at 14 days. The actual results for this endpoint (see attachment) indicate that the percentage change relative to controls is similar at 6.9 ppm and 17 ppm and statistically significant at each dose. A minor revision of the RED chapter is suggested to clarify that adverse effects were observed at 17 ppm as well as at 6.9 ppm.
2. Gowan calculated that the environmental concentration would decrease to approximately the NOEC within about a week after application.

EFED does not reject consideration of the time that a pesticide concentration exceeds a toxicity reference value. An obvious limitation of that kind of calculation is that the magnitude of exceedance is not taken into account. However, on toxicological grounds EFED does not agree that if the concentration can be shown to exceed the NOEC for only about a week (a point that Gowan has not actually established), then the chronic risk concern would be refuted. In general, EFED considers it plausible on toxicological grounds that effects observed after 21 weeks in an avian reproduction study might actually have resulted from exposure during a single week.

3. Gowan estimates that 84% of applied will degrade after one week, averaging over several crops. This is equivalent to a degradation rate $k=0.26/d$ (by solving $1-0.84=\exp(-7k)$), or to a $T_{1/2}=2.65$ days (solving $k=\ln 2/T_{1/2}$), assuming first-order degradation kinetics. For purposes of comparison, EFED used a half-life of 3.2 days, which is the aerobic soil half life.

4. For the results to be compared to those of Gowan, it seems that the data would need to be used in a similar way. EFED views the time-0 concentration values used for ODM to be approximately the 95th percentiles for the distribution in the residue database. An empirical 95th

percentile cannot be calculated from fewer than 20 measurements, but Gowan reports values from individual trials up to about 20 ppm per 0.5 lb applied for corn and alfalfa, or 40 ppm per lb applied. EFED assumed up to 240 ppm per lb applied.

The RED chapter assumed 2 applications at 0.5 lb/a, with a 3 week interval. If ODM is applied only *once* to corn at 0.5 lb ai/A resulting in a time-0 concentration of 20 ppm, and assuming first-order degradation at Gowan's rate of 84% per week, then about 9 days would be required for the concentration to reach the NOEC ($9 = \ln(20/1.8)/k$). EFED would not agree that exceedance of the NOEC for 9 days refutes a chronic risk. The 2-week average EEC would be 5.4 ppm ($= 20 * (1 - \exp(-14 * k)) / (14 * k)$), to be compared to the NOEC of 1.8 ppm.

Gowan states that their results are based on data while EFED's results are based on a theoretical model. Gowan does not say which features of EFED's analysis warrant this distinction. EFED used residue data for the time-0 foliar concentration (albeit from a database involving multiple chemicals), assumed a linear relationship between application rate and initial concentration, and applied a calculation of approximate dissipation. The latter two features are evident in both Gowan's and EFED's analysis. Further consideration of the residue information indicated by Gowan may be given and at later time.

Attachment. The ODM avian chronic toxicity study 40747202: results for weight of 14-day survivors.

		Measured Concentration (Nominal concentration)		
Control		1.8 ppm (3 ppm)	6.9 ppm (10 ppm)	17.3 ppm (30 ppm)
Mean	C = 26.2	T = 25.7	23.2	23.7
num. chicks	13	14	9	14
%Change =100(C-T)/C	--	2% decrease	11% decrease*	10% decrease*

* Statistically significant decrease in mean relative to control based on both Bonferroni t-tests (for 3 comparisons) and Williams test. Tests were one-sided tests for a decrease. Assumptions of parametric tests were tested and not rejected. Error SS =302. (ToxStat results, which agree qualitatively with the SAS results used for the RED chapter.)

We proposed that the text in the RED be revised as follows:

“In the bobwhite quail study, statistically significant differences were noted at the 6.9 treatment level and that the 17.3 ppm treatment level, for the 14 day old survivor weights, number of eggs laid per hen, and the number of eggs set per hen. Both the number of viable embryos and live three week embryos per hen was significantly different at the 17.3 ppm treatment level. Based on these results EFED finds that the avian chronic NOEC is 1.8 ppm.”